number of pharmacies that were flagged as suspicious based on their ordering patterns or other factors. (Controlled Substance Diversion Update, Jeff Henderson, Jan. 23, 2008, at 2.) As a result, the Company ceased distributing to a number of suspicious pharmacies, but also temporarily cut off a few customers that further investigation showed to be potentially legitimate. (*Id.*) The Board was also provided with a detailed action plan for the Company's key anti-diversion measures in the form of a seven-page chart listing the tasks to be completed, the progress thus far, and target completion dates. (*Id.*) The progress included changes to the anti-diversion personnel, processes, and systems, including: hiring additional anti-diversion personnel and reorganizing the anti-diversion group; improving the reviewing and reporting structure; revising certain procedures relating to investigations, communication between departments, and monitoring; and developing enhanced anti-diversion training. (*Id.*)

The Board was also provided with a presentation listing the key anti-diversion measures that had been implemented or were in the process of being implemented. (DEA Update, Jeff Henderson and Ivan Fong, Jan. 31, 2008, at 4.) These measures included the development of heightened criteria for new customers, development and implementation of enhanced training, organizational realignment and hiring of new anti-diversion personnel, conducting investigations on hundreds of existing customers and utilizing outside investigators as needed, launching the IT solution for order review, initiating independent, third-party review, suspending over sixty accounts, implementing order limits for certain drugs, and revising the sales compensation structure to encourage salespeople to report signs of diversion. (*Id.*) The Company also indicated that it was focused on responding promptly to any indicators of diversion ("red flags") and suspicious orders, and maintaining a dialogue with the DEA regarding the new IT system. (*Id.* at 5.)

In February 2008, Fong and Henderson provided an update to the Board highlighting key changes in the anti-diversion system that had already been implemented based on recommendations of outside counsel and other anti-diversion consultants, in the areas of personnel, processes, training, and systems. (Anti-Diversion Update, Ivan K. Fong and Jeff Henderson, Feb. 22, 2008, at 3-4.) These changes included hiring new anti-diversion leadership, reviewing and replacing QRA personnel at distribution centers, and hiring a team of investigators. (*Id.* at 3.) In addition, the Company established procedures to review threshold events, approve new customers, and improve communications between the Sales and QRA teams. (*Id.* at 3.) As a result of these new processes, the Company terminated over 110 customers and rejected six potential new customers. (*Id.* at 4.) Further, the Company initiated comprehensive and ongoing anti-diversion training and continued to roll out the electronic order monitoring system. (*Id.* at 3-4.)

During the May 7, 2008 Board meeting, Fong and Henderson provided the Board with another update describing the progress on key anti-diversion action items, which included the hiring of a Chief Compliance Officer, a Senior Vice President of Supply Chain Integrity, a Vice President, two directors, six investigators, and twenty-four field QRA compliance managers, as well as the implementation of new procedures, training, and an enhanced electronic monitoring system for retail independent pharmacies. (Anti-Diversion Update, Ivan K. Fong and Jeff Henderson, May 7, 2008, at 2.)

The May 2008 presentation also described the Company's newly-established standardized criteria to identify excessive purchases, and its enhanced process for investigating suspicious orders. (Anti-Diversion Update, Ivan K. Fong and Jeff Henderson, May 7, 2008, at 5.) As part of these improvements, the Company conducted site visits of 266 customers, and twenty-one distribution centers, and implemented recommendations made by outside counsel for each. (*Id.*) Further, the Company stopped selling to, and reported, 115 customers. (*Id.*) The Company also completed the first two phases of implementing the electronic monitoring system, which involved refining the thresholds for retail independent pharmacies, and rolling out the remaining classes of trade. (*Id.* at 6.) As a result, from January through March, the Company blocked and investigated 2,760 excessive orders. (*Id.* at 6.) Other improvements to the Company's anti-diversion measures included: the development of educational materials for employees regarding diversion and controlled substance abuse; the establishment of more focused communications between sales, operations, and QRA; the performance of distribution center QRA process and procedural audits relating to controlled substance handling and security; review of the relevant SOPs with QRA personnel; training of 1,700 employees at over 100 different training events; and development and implementation of an on-going training curriculum. (*Id.* at 5.) The presentation included a list of items to be completed in the short-term, which included upgrading the SOPs, completing full implementation of the electronic monitoring system, fully training personnel on anti-diversion requirements and KYC policies, and enhancing the distribution center level security and in-transit processes. (*Id.* at 2.)

Shortly after the May 2008 Board meeting, Fong informed the Board about an investigation by the Ohio Board of Pharmacy, based on allegations that the Company's distribution center in Findlay, Ohio made suspicious sales to a pharmacy in Dublin from December 2006 through March 2007. (Email from Ivan Fong to Cardinal Health Directors, May 29, 2008.) Fong relayed that anti-diversion personnel noticed the increased orders of controlled substances for that pharmacy in February 2007. (*Id.*) The Company conducted a site visit in March 2007 and terminated the customer in April 2007, a few days after the Ohio Board of Pharmacy suspended the customer's license. (*Id.*) Fong communicated the belief that the current anti-diversion controls would have caught the suspicious behavior of this pharmacy much sooner. (*Id.*)

In advance of the August 5, 2008 Audit Committee meeting, Morford provided the Audit Committee with his first Chief Compliance Officer Update, which noted that the role of Chief Compliance Officer had been greatly expanded and described the Company's current procedures for detecting suspicious orders of controlled substances. (Chief Compliance Officer Update, Craig Morford, Aug. 2008, at 2, 10.) This report also noted key accomplishments, including: establishment and implementation of the electronic monitoring system; establishment of the KYC program; KYC training administered to 2,500 employees; and the creation of thirty-eight new anti-diversion positions. (*Id.* at 10.) Finally, the report noted that key priorities for 2009 included rolling out the electronic monitoring system to the remaining classes of trade, finalizing a settlement agreement with the DEA, and bringing the suspended facilities back on line. (*Id.* at 11.)

Morford also provided a Chief Compliance Officer report to the entire Board, which included a review of anti-diversion updates. (Chief Compliance Officer Report, Craig Morford, Aug. 2008.) Among the changes discussed were the expansion of Morford's role as Chief

Compliance Officer, and business leaders throughout the Company being given the "duty, responsibility, and accountability" for making appropriate decisions regarding quality and compliance. (*Id.* at 6.) The Board was also updated on the Company's progress in achieving its goal of establishing a "premier system for identifying, reporting, and blocking suspicious controlled pharmaceutical orders." (*Id.* at 5.) Finally, Morford noted that expanding the electronic monitoring system and establishing sufficient systems to comply with the forthcoming settlement with the DEA were top priorities. (*Id.* at 10.)

In November 2008, Morford informed the Audit Committee that the Company had reached a settlement with the DEA, and explained the Company's obligations under the settlement agreement. (Chief Compliance Officer Q1 Update, Craig Morford, Nov. 2008, at 9, 20-21.) The Audit Committee also learned that training on the KYC procedures and the implementation of those procedures was complete and, as of the end of October 2008, the electronic monitoring system covered 80% of DEA registrants. (*Id.* at 9.) The Company expected to complete the roll out of the electronic monitoring system across the remaining classes of trade by December 2008. (*Id.*) Morford also informed the Audit Committee that DEA compliance inspections were scheduled to begin in January 2009. (*Id.*) To prepare for these inspections, the Company planned to revise and develop SOPs to improve the existing supply chain integrity process. (*Id.*) The Audit Committee was also informed that anti-diversion training was in progress on distribution center and sales SOPs, KYC procedures, and the electronic monitoring system. (*Id.* at 19.) Fong also discussed the DEA settlement and the Company's anti-diversion measures at the next day's Board meeting.

The Audit Committee received another update on the anti-diversion measures in February 2009, including that the electronic monitoring program was rolled out to the additional classes beyond retail independent pharmacies, and that the program was favorably received by the DEA on December 18, 2008. (Chief Compliance Officer Q2 Update, Craig Morford, Feb. 2009, at 12.) The materials also stated that the distribution centers that had been suspended in 2007 and 2008 were back online and that, as part of the settlement with the DEA, the DEA planned to conduct compliance reviews at the Company's corporate headquarters and at several facilities. (*Id.*)

The Audit Committee received an update regarding the DEA inspections in advance of its May 2009 meeting. (Report on Lawsuits and Claims, Stephen T. Falk, Apr. 23, 2009, at 10.) The Audit Committee was informed that in January and February 2009, the DEA had visited the Company's Dublin headquarters and performed compliance reviews of five distribution centers. (*Id.*; *see also* Chief Compliance Officer Q3 Update, Craig Morford, May 2009, at 4.) Further, the Audit Committee was informed that on March 16, 2009, the DEA notified the Company that it considered one of those distribution centers, the facility located in Valencia, California, to be "unsatisfactory," and that the Company met with the DEA to address those concerns on March 19 and submitted a written response to the DEA on March 25. (Report on Lawsuits and Claims, Steve Falk, Apr. 23, 2009, at 10.) In May 2009, Morford informed the Audit Committee that the Company received favorable oral feedback regarding the Valencia facility issues. (Chief Compliance Officer Q3 Update, Craig Morford, May 2009, at 4.)

In August 2009, Morford informed the Audit Committee that the Company completed data reviews for all customers and all necessary customer investigations, and achieved "superior

results" on routine DEA cyclical inspections of five distribution centers. (Chief Compliance Officer Q4 Update, Craig Morford, Aug. 2009, at 4.) Morford also provided an update on the Company's anti-diversion efforts to the entire Board. (Annual Compliance Program Review, Craig Morford, Aug. 2009.) The update stated that the Company had "[d]esigned and implemented an effective Suspicious Order Monitoring Program across all classes of trade," successfully completed routine DEA cyclical inspections of five distribution centers with "superior ratings," and developed regulatory operations SOPs. (*Id.* at 5.) The Board was also informed that 3,600 employees underwent anti-diversion training during fiscal year 2009.[38] (*Id.* at 22.) In October 2009, the Audit Committee received a compliance update noting that the routine DEA cyclical reviews of distribution centers to date had "gone well." (Quarterly Compliance Program Update, Craig Morford, Oct. 27, 2009, attaching Compliance: Quarterly Compliance Program Update, Craig Morford, Nov. 2009, at 2.)

In October 2010, Morford provided the Audit Committee with an Annual Quality and Regulatory Report, which included an overview of the then-current regulatory environment. (2010 Annual Quality and Regulatory Report, Craig Morford, Oct. 2010, at 4-5.) Morford noted that the DEA had increased its focus in "high risk" states, including Florida. (*Id.* at 4.) The expected areas of focus for the DEA were dispensing pain clinics, selected pharmacies servicing non-dispensing pain clinics, and distributors servicing "bad" pharmacies. (*Id.*) In response to the increased focus in Florida, a task force was assigned to evaluate all Florida customers, and work with customers to address potential diversion risks and/or terminate customers that posed too high of a risk. (*Id.* at 8.) During the ensuing months, the Company expected the DEA to focus on the Company's operational controls and the overall effectiveness of its anti-diversion program. (*Id.* at 4.) The report also noted that the DEA had conducted twenty-five routine cyclical inspections over the previous twelve months, which resulted in no "observations," or negative findings. (*Id.* at 7, 10.)

Morford provided the full Board with a review of the main anti-diversion risks in advance of the November 2010 Board meeting. (Review of Key Risks – November Board Meeting, Craig Morford, Oct. 26, 2010, attaching Enterprise Risk List, Nov. 2010.) He also noted the ways those risks were being mitigated, including: the electronic monitoring program, which was overseen by experienced pharmacists; the KYC procedures; the advanced analytics driving focused customer visits; the focused approach in high risk areas, such as Florida; the plans for business continuity; and the continued monitoring of DEA meetings. (Enterprise Risk List, Nov. 2010, at 1, 7.)

On July 26, 2011, Morford sent a memorandum to the Board regarding key initiatives and accomplishments in fiscal year 2011. (Pre-read for Key Risks and Annual Compliance Review, Craig Morford, July 26, 2011.) Among other things, the memorandum described the enhanced electronic monitoring system, which decreased "false positives," i.e., legitimate customers or

[38] The training efforts continued, and in July 2010, the Directors were informed that anti-diversion training had been administered to many additional employees. (Annual Update – FY '10, Ethics and Compliance Program, Craig Morford, July 27, 2010, at 3.)

orders that were flagged as suspicious.[39] (*Id.* at 5.) On the same day, the Board also received a memorandum from Morford and Falk regarding a customer who wanted to do business with Cardinal Health and was upset that the Company had refused, based on a determination that the pharmacy posed a high risk of diversion. (Communication from Pharmacy Owner, Craig Morford and Steve Falk, July 26, 2011.)

In advance of the November 2011 Board meeting, Morford and Quintero provided an update on regulatory matters, including the regulatory environment and increased focus on distributors. (Annual Quality and Regulatory Report, Craig S. Morford, Oct. 25, 2011, at 2-3.) The update stated that the DEA conducted twelve routine cyclical inspections during fiscal years 2011 and 2012, which resulted in four "observations," or negative findings.[40] (*Id.* at 5.) The update also identified the risk of the DEA's aggressive posture on anti-diversion and the Company's major mitigating factors, including: the development of an advanced analytics program to better predict diversion; the formation of SWAT teams to evaluate high risk regions, including Florida; the hiring of former DEA senior counsel as a consultant to the Company; and close coordination of senior business leaders in managing risk. (*Id.* at 6.) Further, the update discussed key accomplishments in the Company's anti-diversion program during fiscal year 2011. (*Id.* at 10.) In particular, the Company underwent five successful DEA cyclical inspections and the DEA had not issued any findings regarding the SOM system for the previous three years. (*Id.*) The update also stated that the Company had reduced impact to legitimate customers by increasing accuracy through advanced analytics, including the introduction of a new model to predict the probability of a customer engaging in diversion. (*Id.*) As a result, the incidence of flagged events was reduced by 2,509, or 37%, from fiscal year 2010 to 2011. (*Id.*) Additionally, during fiscal year 2011, forty-seven suspicious orders were identified and reported to the DEA, thirty-six customers were restricted from purchasing controlled substances, and eighteen potential new customers were denied from purchasing controlled substances. (*Id.* at 10-11.)

A separate report prepared for the November 2011 Board meeting further discussed the regulatory risks posed by the DEA's aggressive posture and noted that the Lakeland distribution center received an investigational warrant on Oct. 26, 2011. (*See generally*, 2011 Annual Quality and Regulatory Report – Pharma Segment, Craig Morford and Gilberto Quintero, Nov. 2, 2011.) The report included a summary of the Company's anti-diversion initiatives over the last four years, including the use of statistics and advanced analytics to help make determinations regarding customer risk, noting that the Company had made significant monetary investments in the new system and engaged many additional employees. (*Id.* at 5.) The report noted that since 2007, over 300 pharmacies had been terminated and reported to the DEA as suspicious, and fifty of those were in Florida.[41] (*Id.*)

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[39] The prior system resulted in many more "false positives" and legitimate customers being terminated as diversion risks. The Company implemented changes in 2011 that refined the electronic monitoring system and increased its accuracy.

[40] *See supra* note 30 (discussing the letters of admonition addressing operational compliance concerns).

[41] In addition to the updates discussed above, the Board and Audit Committee also received updates regarding compliance issues and the status of the Company's anti-diversion efforts at the following

VI. THE 2012 ISO

A. The Events Surrounding the 2012 ISO

The 2012 ISO asserted that from January 2008 through December 2011, Cardinal Health sold excessive amounts of oxycodone to its top four retail pharmacy customers, all located in Florida and serviced by the Company's Lakeland facility: two CVS stores, CVS/Pharmacy #00219 ("CVS 219") and CVS/Pharmacy #05195 ("CVS 5195"), and two independent retail pharmacies, Caremed Health Corporation ("Caremed") and Gulf Coast Pharmacy ("Gulf Coast").[42] (2012 ISO at 2.) The 2012 ISO alleged further that Cardinal Health "failed to conduct meaningful due diligence" of its retail pharmacy customers, including its chain customers, and "failed to detect and report suspicious orders of oxycodone products by its pharmacy customers."[43] (*Id.* at 3.)

The Company's electronic monitoring system flagged the four pharmacies at issue in the 2012 ISO, and the anti-diversion group reviewed the pharmacies' orders and communicated with the pharmacists at Caremed and Gulf Coast and with the CVS loss prevention department. Cardinal Health ceased distributing controlled substances to Caremed and Gulf Coast months before the 2012 ISO, and the quantity of oxycodone being shipped to CVS 219 and CVS 5195 had diminished significantly by that time.

With respect to Gulf Coast, Company personnel conducted frequent site visits, including in August 2008, April 2009, December 2009, October 2010, and February 2011. (Apr. 13 Moné Decl. ¶ 59.) Gulf Coast was located in a hospital medical complex and served emergency room patients, four pain management clinics, and three nursing homes and assisted living facilities, making the high volumes seem reasonable. (Feb. 6 Moné Decl. ¶ 43.b.) Further, in 2009, the hospital added over 300 beds. (Feb. 6 Moné Decl. ¶ 43.c.) The pharmacy provided drug utilization reports for December 2009 and July 2010, which the anti-diversion group reviewed and concluded were consistent with legitimate use. (Feb. 6 Moné Decl. ¶ 43.e.)

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meetings: the May 6, 2009 Board meeting; the January 31 and February 1, 2011 Audit Committee meeting; the May 3, 2011 Audit Committee Meeting; and the October 25, 2011 Audit Committee Meeting.

[42] According to the ISO, the amount of oxycodone that the Company was distributing to these pharmacies "well exceeded" the average amount of oxycodone that the Company's Florida retail pharmacies were receiving. (2012 ISO at 2.) The affidavit in support of the Administrative Inspection Warrant served on the Lakeland facility on October 26, 2011 also relied heavily on volume and comparison of sales averages. (*See* Affidavit for Administrative Inspection Warrant, Oct. 25, 2011, ¶¶ 5-6.) However, according to the DEA's own data, the average number of dosage units of oxycodone distributed from the Company's Lakeland facility to each of Cardinal Health's Florida pharmacy customers was far less than the average amount purchased by Florida pharmacies from late 2008 through 2011. (*See* Plaintiff Cardinal Health, Inc.'s Notice of Submission Pursuant to the Court's Order of February 16, 2012, at 6, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 20, 2012) (including chart titled "Oxycodone Dosage Units Purchased by Pharmacies").)

[43] This section provides a brief summary of the events at issue in the 2012 ISO. A more detailed review of the DEA's allegations can be found in the Leonhart Declaration.

During an investigation in April 2009, the investigator, Vincent Moellering, learned some information about Gulf Coast from one of its competitors that caused him to question the pharmacy's orders. (*See* Feb. 6 Moné Decl. ¶ 43.a.) Although Moellering could not substantiate the information, and did not observe any other indicia of diversion, he called a local DEA agent and relayed the information. (Memorandum from Vincent Moellering to File re: Gulf Coast Medical Pharmacy, May 7, 2009, at 6.) Moellering did not hear back from the agent after that conversation. (Apr. 13 Moné Decl. ¶ 64.) The following year, after another site visit, Moellering rated Gulf Coast as a "high risk," and requested permission to contact the DEA regarding the pharmacy, because he was not "convinced that the owner [was] being forthright about his customer's [sic] origin or residence." (Report of Investigation re: Gulf Coast Medical Pharmacy, Vincent Moellering, Oct. 13, 2010, at 3; Apr. 13 Moné Decl. ¶ 64.) Moné told Moellering that the DEA did not have information regarding the addresses of the pharmacy's patients. (Apr. 13 Moné Decl. ¶ 64.) Moellering then contacted the pharmacy and requested a list of all physicians prescribing C2 – C5 drugs, and received a list of physicians in response. (Memorandum from Vince Moellering to File re: Gulf Coast Medical Pharmacy, Nov. 3, 2010.) Steve Morse, the Director of Investigations, determined that the information showed that "[t]he primary prescribers identified by the pharmacy owner [were] local, one exception being an orthopedic surgeon," and thus rated the pharmacy as a "medium risk." (Addendum to Report of Investigation dated 10/13/10 Gulf Coast Medical Pharmacy, Steve Morse, Nov. 9, 2010.)

In February 2011, Morse conducted a follow-up site visit of Gulf Coast and again rated the pharmacy as a "medium risk." (Report of Investigation re: Gulf Coast Medical Pharmacy, Steve Morse, Mar. 24, 2011.) However, in Fall 2011, Mallinckrodt, an oxycodone manufacturer, provided Cardinal Health with information indicating that Gulf Coast was purchasing oxycodone from other wholesalers in addition to Cardinal Health. (Apr. 13 Moné Decl. ¶ 69.) In addition, Gulf Coast was unable to verify its claim that the local Sheriff's Office supported the consolidation of prescriptions from four nearby health facilities through Gulf Coast. (*Id.* ¶ 70.) As a result, the Company terminated Gulf Coast on October 5, 2011. (*See* Feb. 6 Moné Decl. ¶ 43.f.)

The Company also conducted site visits and obtained drug usage reports for Caremed. (Feb. 6 Moné Decl. ¶ 44.) Caremed was located in a community health center with over one hundred doctors' offices, and served a sizeable elderly population. (Feb. 6 Moné Decl. ¶ 44.a.) Health centers typically offer varied treatment, including pain management. Caremed experienced threshold events in February and March 2010. (Apr. 13 Moné Decl. ¶ 52.) Morse communicated with Caremed's pharmacist, who explained that the pharmacy was experiencing growth due to a number of factors and provided a drug dispensing report. (Apr. 13 Moné Decl. ¶ 52.) Morse raised the threshold for Caremed in response. (Apr. 13 Moné Decl. ¶ 52.) In May 2010, an investigator performed a site visit of Caremed and concluded that the pharmacy posed a low risk of diversion because the significant elderly population in the surrounding area justified the volume of oxycodone prescriptions. (Apr. 13 Moné Decl. ¶ 53.) The pharmacy's monthly purchases of oxycodone increased between June and December 2010, and the Company sent an investigator to the pharmacy in January 2011. (Feb. 6 Moné Decl. ¶ 44.b.) The investigator again concluded that the pharmacy posed a low risk of diversion, based in part on the relatively low percentage of prescriptions that were paid for in cash. (Apr. 13 Moné Decl. ¶ 54.) However, Caremed again prompted concern in September 2011, when the drug utilization report showed a significant increase in the monthly prescriptions for oxycodone. (Feb. 6 Moné Decl. ¶

44.b.) When Moellering visited the store in September 2011, he learned that the physicians who were writing the prescriptions at issue were not located at the health center, and the Company thus terminated Caremed as a customer on September 26, 2011. (*See* Feb. 6 Moné Decl. ¶ 44.c.)

With respect to the CVS stores at issue in the 2012 ISO, the electronic monitoring system identified oxycodone ordering patterns for these stores that required explanation in late Summer and early Fall 2010. (Apr. 13 Moné Decl. ¶ 73.) In August 2010, Moné met with the Company's primary contact at CVS, Brian Whalen, about certain CVS stores that required investigation, including CVS 219. (Quintero Decl. ¶ 14; Apr. 13 Moné Decl. ¶ 73.) In September 2010, CVS informed the Company that their Loss Prevention team had reviewed the stores and had not uncovered any issues, and that the increase in sales for CVS 219 was due to the closing of other pharmacies in the area. (Quintero Decl. ¶ 14; Email from Paul Farley to Michael Moné re: CVS #0219, Sept. 30, 2010.) In October 2010, Christopher Forst, the Director of Pharmacy Assessment, visited CVS 219 without informing CVS and did not see any indicia of diversion. (Quintero Decl. ¶ 15; Email from Christopher Forst to Michael Moné re: CVS #219, Oct. 6, 2010.) Further, Moné concluded that the volumes of oxycodone being distributed to the two CVS stores did not appear unreasonable in light of the stores' large size, and the fact that they were located in busy suburban neighborhoods, and were open seven days per week. (Feb. 6 Moné Decl. ¶ 54.) Subsequently, in August 2011, the Company identified CVS 219 and 5195 as outliers and scheduled a meeting with CVS in late August, but the meeting was later rescheduled for October. (Quintero Decl. ¶¶ 21-22.) On October 12, 2011, in response to an email from Moné raising concerns about several CVS stores, including CVS 5195, CVS stated that CVS had conducted a comprehensive review and had not found any evidence of diversion. (Apr. 13 Moné Decl. ¶ 77; Quintero Decl. ¶ 22; Email from Karen Gibbs to Michael Moné re: Florida Stores, Oct. 12, 2011.)

On October 18, 2011, the DEA served warrants on CVS 219 and CVS 5195, and Cardinal Health lowered the oxycodone thresholds for these stores by significant amounts in November and December, respectively. (Apr. 13 Moné Decl. ¶ 78.) Further, in Fall 2011, CVS stopped filling prescriptions written by twenty-two Florida doctors. As a result, the Company's distribution of oxycodone to CVS 219 and 5195 fell drastically in November and December 2011. (Apr. 13 Moné Decl. ¶ 80.)

B. Reaction to the 2012 ISO

1. General Reactions Within the Company

In general, the reaction to the 2012 ISO was one of surprise and frustration, for a number of reasons.[44] First, the overall belief among management and within QRA was that the anti-diversion program was effective, and that the Company was meeting or exceeding its obligations. The DEA visited the Company's corporate headquarters in early 2009 and reviewed the new anti-diversion program. In addition, the DEA conducted at least twenty cyclical

[44] A February 15, 2012 email to the Board, sent on behalf of Falk, included a transcript of a investor call which expressed the Company's surprise and frustration with the 2012 ISO in light of the Company's extensive improvements to the anti-diversion systems since 2007. (Email from Steve Falk to Cardinal Health Directors, Feb. 15, 2012.)

inspections of Cardinal Health distribution centers from 2008 through 2011, and did not issue any negative findings regarding the anti-diversion measures in place at those facilities. Moreover, in 2010, the Company retained John Gilbert, an attorney who had previously served in the diversion section of the DEA's Office of Chief Counsel, to perform an independent assessment of the anti-diversion system. Gilbert recommended four changes to the system, and the Company implemented each of those changes. All of these factors contributed to the sense that the Company had been successful in building the anti-diversion system.

Second, before the 2012 ISO, the Company was operating under the impression that if the Company performed its diligence on customers, it could rely on the pharmacist's expertise and judgment in analyzing customers and orders. However, the 2012 ISO was based almost entirely on the volumes that were shipped to the four pharmacies at issue, indicating that a shift needed to be made to viewing large volume orders as "per se" suspicious. Third, one of the difficulties the Company faces in detecting suspicious orders is a lack of information. HIPAA precludes pharmacies from sharing patient-specific information, including information about prescriptions, with distributors. Further, the DEA does not inform other distributors when one distributor terminates a customer, because it could be subject to civil liability for disclosing such information. The Company also is not privy to information regarding whether pharmacies are purchasing controlled substances from multiple distributors and the aggregate quantities of controlled substances purchased by pharmacies. (Morford Decl. ¶ 19.) Fourth, the Company had terminated the two retail independent pharmacies at issue in the 2012 ISO months before it was issued, and significantly reduced the quantities being shipped to the two CVS stores at issue.

There was also the impression among some in management that, in hindsight, Morse and Moné should have terminated the independent pharmacies at issue in the 2012 ISO sooner. However, the system functioned properly by flagging each of the pharmacies at issue, and Morse and Moné made the decisions not to terminate those pharmacies in good faith, after reviewing the pharmacies and orders at issue.

In response to the 2012 ISO, the Company has attempted to reduce subjectivity in the system, and implement more objective criteria and procedures for reviewing pharmacies and orders. The view within management is that although there were good controls in place before the 2012 ISO, the Company has had to adjust certain measures to bring them in line with the current state of anti-diversion.

2. Modifications to Anti-Diversion Policies and Procedures

a. Personnel

In the months following the 2012 ISO, Moné was moved from his position as Vice President of Anti-Diversion into a position as attorney in the regulatory group, focusing on such things as training, policy development, and the Company's outreach efforts with boards of pharmacy. Moné continues to be recognized for implementing many effective anti-diversion measures, and possessing valuable knowledge and expertise. However, under Moné, the evaluation of customers and orders had been heavily focused on the clinical expertise and subjective judgment of the pharmacists in the anti-diversion group. The goal after the 2012 ISO

was to move towards assessing customers based more on objective criteria and a practical knowledge about the business.

Morse was moved from his position as Director of Investigations to a position in regulatory management, outside the arena of controlled substance anti-diversion. The view was that Morse was not as strategic as his former position required and there were questions about his judgment. Specifically with respect to the pharmacies at issue in the 2012 ISO, management felt that Morse should have reviewed Gulf Coast more thoroughly.

b. Monitoring Customers

The Company has continued its efforts to enhance the electronic monitoring system. In or around September 2012, the system moved to a linear regression model, which uses volume as a dependent variable and other factors as independent variables.

As a result of the Memorandum of Agreement entered into with the DEA in 2012 (the "2012 MOA"), the Company has also made changes to the policies with respect to adjusting thresholds. The 2012 MOA requires a "two-person concurrence . . . before increasing thresholds for higher volume customers for specific drug classes." (2012 MOA at 3.) In general, there has been a concerted effort to treat threshold events more consistently and objectively. The review of thresholds is less of a subjective analysis based on the customers' ordering history and more focused on how the customers' prescription drug count compares with the national average. Accordingly, the analysts in Rausch's group are now responsible for responding to threshold events. Analysts will adjust thresholds in a limited set of circumstances, by applying objective, numerical criteria. Generally, if a pharmacy exceeds its threshold and the pharmacy or order does not fall within those limited circumstances in which an analyst can adjust the threshold and release the order, the order will not be filled and will be reported to the DEA as suspicious.

Pharmacists are responsible for responding to threshold events for long term care and hospital pharmacies, which do not lend themselves to the objective criteria applicable to retail pharmacies. Pharmacists are also responsible for continually reviewing the largest volume customers. In addition, the Company created a Large Volume-Tactical and Analytical Committee ("LV-TAC") in response to the 2012 MOA, to review "higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida." (2012 MOA at 3.) LV-TAC holds monthly meetings and is comprised of numerous members across various departments. (*See* 2012 MOA at 3.)

During 2012, the salespeople started receiving additional information about their customers' ordering within a program called "Winwatcher," a tool designed to help the salespeople track their customers and sales goals, among other functions. Winwatcher notifies salespeople when a customer's percentage of accrual of its threshold amount (for any controlled substance or listed chemical that is assigned a threshold) surpasses the percentage of completion for the month (e.g., a customer reaches 60% of its threshold on the fifteenth of the month). Winwatcher always shows customers' percentage of accrual for oxycodone, hydrocodone, and alprazolam, regardless of the time of the month. Further, although investigators and pharmacists

at times conducted surveillance visits of chain stores before the 2012 ISO, it is now standard procedure for salespeople to conduct regular surveillance visits of chain pharmacies.[45]

c. On-Site Investigations

In or around March or April 2012, the report used by investigators in conducting site visits changed from Word documents to Excel documents. The new report is an interactive document that asks for specific, objective data, thereby removing a great deal of subjectivity from the investigation process. There has also been more standardization in the procedures for site visits, and additional investigators have been hired as part of a concerted effort to shorten the time for completing investigations. Additionally, in an effort to increase transparency among departments, there is more frequent communication between investigators, pharmacists, and salespeople, about specific pharmacies and about whether and when a site visit is going to be conducted.

Moreover, the current Director of Investigations now reviews each site visit report and makes a concerted effort to provide timely feedback and guidance. Despite the requirement in the SOPs issued in 2008 that the Director of Investigations review each site visit report, Morse did not do that.

d. Reporting Suspicious Orders

The prior approach to reporting suspicious orders to the DEA was to report an order as suspicious when the customer appeared suspicious, i.e., report an order that, after review, led the Company to terminate the customer as an unreasonable risk of diversion. The current approach is to report every order that is deleted and not filled, unless the order is the result of an entry error.

VII. RECOMMENDATIONS ON MERITS OF ALLEGATIONS AND OTHER FACTORS TO BE CONSIDERED

A. Recommendations on Merits of Allegations

Based on the factual information the Committee gathered during its investigation, and its understanding of the applicable law, the Committee does not believe that it is in the best interest of the Company to pursue claims for breach of fiduciary duty against the present and former directors named in the Demand Letter. The investigation shows that the Board at all times acted diligently and in good faith to fulfill its duties to the Company and the Company's shareholders.

The Letter alleges that the 2012 ISO was the result of a failure by the Company "to implement systems to detect and prevent the diversion of controlled substances into the illegal market" in accordance with the CSA and the 2008 MOA. (Demand Letter at 1, 10.) Further, the Letter alleges that the Directors and Officers of the Company "breached their duties of loyalty

[45] Since the 2012 ISO, the chains are more willing to collaborate with the Company on anti-diversion issues and the Company now receives more detailed information for individual chain stores.

and care when they knowingly and/or recklessly failed to establish" such a system of internal controls. (*Id.* at 10.)

As discussed, (*see supra* Part II), Ohio law provides that directors can be liable for damages only if they acted or failed to act with deliberate intent to cause injury to the corporation or with reckless disregard for the best interests of the corporation. *See* Ohio Rev. Code § 1701.59(E). Directors satisfy their obligation to remain informed of the corporation's activities if a reasonable information and reporting system exists within the company. *See Caremark*, 698 A.2d at 970-71. Where a reporting system exists, directors can be liable for breach of their oversight duty only if they ignore red flags that come to their attention warning of compliance problems. *See Stanley*, 2012 WL 5269147, at *6.

First, as this report makes clear, the Company implemented an extensive and robust system of internal controls to detect and prevent the diversion of controlled substances following the 2008 MOA, at a cost of approximately $25 million. The Board purposed for the Company to have a premier anti-diversion system. The Company brought in new management with extensive leadership, regulatory, and pharmaceutical experience, including Craig Morford, Gilberto Quintero, and Michael Moné, and hired experienced investigators and pharmacists to review potential new customers and monitor existing customers. The Company implemented an electronic monitoring system and set threshold ordering limits for customers based on statistical analyses of ordering data, and continued to improve the system and the underlying data. The Company developed a logistical regression model to compare existing customers to customers that had been terminated for posing unreasonable risks of diversion and hired a University Professor to validate the model. A centralized database was created to store and track data on customers and orders, thereby facilitating the monitoring process. Extensive policies and procedures were implemented for the anti-diversion group, salespeople, and personnel in the distribution centers. The Company administered anti-diversion training to thousands of employees. The Board was fully informed of the implementation of the anti-diversion measures, and received regular and detailed progress reports along the way.

Second, there were no red flags that the new anti-diversion controls were inadequate. The reaction of the Board, senior management, and QRA personnel to the 2012 ISO was one of surprise. The Company benchmarked the system with its competitors to the extent that it could, and hired outside consultants to test the system. By all accounts, management and QRA personnel were of the impression that the anti-diversion system was meeting or exceeding the Company's obligations to detect and report suspicious orders. Further, the Company received little, if any feedback from the DEA about the new system. The DEA reviewed the new anti-diversion system in early 2009 and inspected five distribution centers as part of the 2008 MOA. Although there were some initial concerns with one of the facilities, the Company rectified the issues and the DEA did not bring any formal proceedings. Moreover, the DEA conducted numerous routine cyclical inspections of the Company's distribution centers from 2008 through the end of 2011, and did not issue any negative findings regarding the anti-diversion measures. In fact, the DEA made positive comments during some of the inspections, indicating that the inspectors conducting those inspections were impressed, or at least satisfied with the compliance measures that were in place at the distribution centers. Senior management informed the Board that the inspections had been "successful" and that there were no negative findings regarding the SOM system from 2008 through 2011. In addition, management informed the Board that the

electronic monitoring system flagged thousands of orders and led the Company to terminate and report many customers, and reduce the volume being distributed to many other customers. The Board was also informed that enhancements to the system in 2011 increased the accuracy of the system and reduced the number of false positives by a significant amount.

Indeed, the Demand Letter fails to identify a single red flag following the 2008 MOA that would have indicated that the Company's diversion controls were inadequate. Instead, the Letter tries to draw a connection between the allegations at issue in the 2007/2008 Action and the allegations at issue in the 2012 ISO. In other words, the issues that existed before the 2008 MOA were the red flags that the Company's anti-diversion controls were inadequate leading up to the 2012 ISO. This reasoning fails for two key reasons. First, the Company undertook a complete overhaul of its anti-diversion measures following the 2008 MOA, and implemented an entirely new system. The facility at issue in the 2012 ISO, the Lakeland facility, was reinstated in 2008 and underwent a "Compliance Review" in 2009 as part of the 2008 MOA and a cyclical inspection in 2010, both without incident. Second, the events at issue in the 2012 ISO were different from those at issue in the 2007/2008 Action. The 2012 ISO involved the sale of oxycodone, not hydrocodone as in the 2007/2008 Action. Further, the pharmacies at issue in 2007/2008 Action were different from those at issue in the 2012 ISO. Finally, the 2012 ISO apparently stemmed from an unannounced shift by the DEA to a strict emphasis on volume, both for retail independent pharmacies, as well as for chain pharmacies.[46]

Moreover, the facts surrounding the pharmacies at issue in the 2012 ISO make clear that the system did not fail, but largely succeeded. Indeed, the electronic monitoring system alerted personnel to the increased ordering of each of the pharmacies at issue in the 2012 ISO, and at least one investigator alerted his superiors to certain indicators of diversion at the independent pharmacies. Ultimately, the Company stopped shipment to the two independent pharmacies at issue months before the Company received the 2012 ISO, and the Company's oxycodone sales to the two CVS stores had also drastically decreased by that time. Moné and Morse decided, after investigating the pharmacies and orders, not to terminate those customers for a period of time. The law does not hold directors liable for the judgment calls that each employee renders in executing the Company's policies and procedures. The directors were obligated to ensure that a reasonable information and reporting system existed. The Company implemented a robust system of internal controls to detect and report suspicious orders in accordance with the CSA and the 2008 MOA, and the directors were well-informed of those measures.

Because the directors did not fail to act in the face of any red flags that the Company's anti-diversion controls were inadequate, let alone fail to act with a deliberate intent to cause harm to the Company or with reckless disregard for the best interests of the Company, the Company cannot recover monetary damages from the directors. (*See* Ohio Rev. Code § 1701.59(E).)

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[46] The 2007/2008 Action involved retail independent pharmacies involved in "internet pharmacy" activity and such activity was, for the most part, readily apparent from viewing the pharmacies' websites, and from the fact that the prescribers were outside the area where the prescriptions were being filled.

B. Other Factors to Be Considered

The Committee also concludes that a review of other factors supports its determination that litigation of the sort requested in the Demand Letter is not in the best interests of the Company. The Committee employed its business judgment to consider all of the corporate interests that may weigh in favor of pursuing the proposed action.

The legal and factual deficiencies of the proposed action, as outlined above, would make it likely that the action would be dismissed before a decision on the merits, or that the action would conclude with a finding that the directors fulfilled their fiduciary duties to the Company. Further, the proposed action would be certain to consume tremendous Company resources. It is probable that pretrial discovery would last many months, and involve extensive document discovery, as well as discovery disputes and motion practice. Many, if not all of the twenty-two present and former Board members named in the Demand Letter would be deposed, as well as many officers and other personnel. It is also reasonable to assume that the parties would retain expert witnesses. In addition, the proposed action would distract management and employees from their daily responsibilities. Such distraction would result from the time and effort required to participate in the litigation, as well as the uncertainties created by criticisms of the Company's anti-diversion policies and procedures, and the execution of those policies and procedures by personnel.

Moreover, it is likely that the Company would be obligated to indemnify the directors for their costs in defending against the proposed action. All but two of the directors named in the Demand Letter signed an Indemnification Agreement, which provides that the Company may indemnify a director for costs and expenses he or she reasonably incurs in an action in which the director is made a party as a result of serving as a director of the Company, except where the director's conduct is found "to have been knowingly fraudulent, deliberately dishonest, or willful misconduct."[47] (*See* Indemnification Agreement §§ 1-2.) Because the directors acted in good faith at all times and diligently fulfilled their duties to the Company, the Committee concludes that the Company would likely be required to indemnify the directors for reasonable expenses they would incur in defending against an action of the sort requested in the Demand Letter. (*See id.*; *see also* Ohio Rev. Code § 1701.13.) The Committee finds that the expense of reimbursing the directors for litigation costs weighs against accepting the demand for claims with limited probability of success.

CONCLUSION

For the foregoing reasons, the Special Committee recommends that the Company not pursue the action requested by the Demand Letter.

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[47] Dave King and Clayton Jones, the most recent members of the Board, are entitled to indemnification under § 6.1 of the Restated Code of Regulations of Cardinal Health, Inc., which similarly provides for indemnification of costs and expenses that a director actually and reasonably incurs in an action where the director was a made a party as a result of his or her position as director.